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(71)(72) Applicant and Inventor: CORTESE, Armand, F. [US/US]; Apartment 30B, 1385 York Avenue, New York, NY 10021 (US).

(74) Agents: JACKSON, Robert, R. et al.; Fish & Neave, 1251 Avenue of the Americas, New York, NY 10020 (US).

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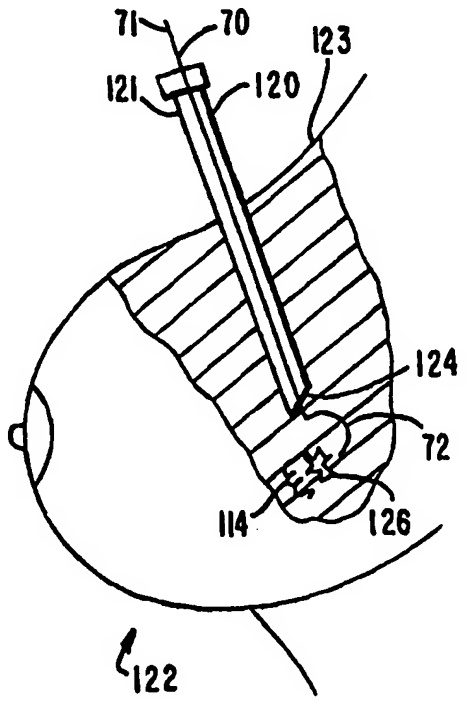
(54) Title: MARKER FOR INDICATING THE LOCATION OF IDENTIFIED TISSUE

(57) Abstract

A method and an apparatus for marking a region of concern in living body tissue to provide improved surgical guidance during biopsy procedures and to provide preliminary verification of recovery of targeted tissue sample. A self–anchoring marker (114) is deployed in the region of concern by using an indicator wire (70) to urge it through a hollow tube (120) inserted through the skin. The indicator wire (70) also has an anchoring mechanism (72) on its tip and is further fed through the tube (120) after deployment of the marker (114) until it is also anchored in the tissue. The tube (120) is then removed, leaving the indicator wire (70) and the marker (114) in place. Unlike the wire (70), the self–anchoring marker (114) is not subject to displacement by movement of the patient and thus provides an indication of post–insertion displacement of the indicator wire (70). It also provides verification of successful sampling when used in conjunction with medical diagnostic or other sensing devices.



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MARKER FOR INDICATING THE LOCATION OF IDENTIFIED TISSUE

Background of the Invention

This invention relates to surgical biopsy of human or animal body tissue and, more particularly to a method and apparatus for indicating the location of a concealed lesion and guiding a practitioner to the identified tissue during a surgical biopsy procedure in order to facilitate excision of such a lesion or other suspect tissue.

While the invention relates to the removal of samples or other identified tissue from body tissue in general, for convenience herein it will be discussed in terms of its relation to the biopsy of suspected cancerous or precancerous lesions from the human breast.

When an abnormality, usually in the form of a lump or a lesion, is discovered in the breast, it is desirable to extract a sample for diagnosis to inform a medical treatment plan. It is of primary importance that the sample be obtained during the initial surgical

procedure because, if subsequent sampling is necessitated, the cutting, suturing, cauterization, and mechanical manipulation of the surgery typically causes the quality of the surgical field to degenerate and thus decreases the favorableness of the conditions for finding and sampling the lesion during subsequent attempts. Additionally, further surgery requires a delay for the patient to heal and thus further reduces the prospects for timely treatment.

Before X-ray mammography and ultrasonic examination of the breast became common, most breast abnormalities were recognized in the form of an easily identifiable lump. If it were suspected to be malignant, it may have been sampled successfully in a straightforward manner because a lump is easily felt and seen. However, with the improvement of diagnostic techniques such as mammography and ultrasound, extremely small abnormalities of the breast became detectable, thus introducing the possibility of the removal of identified tissue at such an early stage of development of a disease that the likelihood of a cure was increased. However, because these less distinctive lesions were not palpable or visible, standard biopsy techniques were not capable of reliable yielding a successful sample.

More advanced techniques have been developed to define the location of such lesions and guide the surgeon (a term used herein to also include supporting technicians and practitioners). These techniques, known as visual mapping, involve drawing markings on the breast based on information from radiological and sonographic films. However, the location of the identified tissue usually can be ascertained using visual mapping with resolution no greater than a breast

quadrant. Thus, exploratory cutting is required in the estimated vicinity of the target and it is necessary to excise a "generous" sample of the targeted region to improve the likelihood of obtaining a specimen of the lesion, thus generating substantial trauma for the patient. Nonetheless, the sample often fails to contain the identified tissue.

In response to the shortcomings of these visual mapping techniques, it has become known to insert a straight sharp needle, such as used for routine blood collection, into the breast to guide the surgeon to the target hidden within. Again using preoperative films to estimate the location of the lesion, the tip of the needle is placed as close as possible to the target spot while the portion of the needle that remains outside the breast is secured to the skin with adhesive tape. Following the shaft of the needle, the surgeon dissects down to the tip embedded in the target and excises the lesion.

This straight needle method also has significant shortcomings. The smooth needle is not anchored in the internal breast tissue and is susceptible to being inadvertently withdrawn from the breast during patient manipulation. More insidiously, if the needle tip wanders away from the target, but the entire needle does not completely pull out of the breast, the surgeon may accidentally be led to excise the wrong sample. The potential for the needle to cause injury to medical personnel or the patient is a further disadvantage of this approach.

In a further development, the sharp needle has been replaced by a soft, blunt-ended guide wire or tissue location indicator equipped at its end with a hook or a barb. In this approach, a sharp needle is

initially inserted into the breast and the tip is placed into or near the target lesion as in prior methods. Then, through the rigid, hollow needle shaft, a soft guide wire is carefully threaded until it emerges from the tip. The end of the guide wire, equipped with a springlike hook that is compressed in the bore of the needle, unfurls upon deployment through the target end of the needle and becomes locked into the lesion or nearby tissue.

On determination of proper placement, the needle is withdrawn from the breast leaving the barbed guide wire in place. The wire is then further secured by fastening the portion protruding from the breast to the skin with adhesive tape. Then, in surgery, the wire is used as a guide to the location of the identified tissue. Because the guide wire is more pliable than the straight needle, and since it is anchored inside the breast tissue, the likelihood of displacement of the guide wire is reduced.

In spite of the improved reliability offered by the guide wire method, the soft wire also remains susceptible to displacement and may lead to an unsuccessful biopsy procedure and the negative consequences described above.

Therefore, it is desirable to be able to indicate the location of identified tissue and guide the surgeon to the region of concern containing the identified body tissue by a tissue location indicator and to further enable the surgeon to determine if the indicator was displaced after its insertion and before tissue sampling or removal. It is also desirable to enable the surgeon to pinpoint, with the aid of visual, radiographic, imaging, scanning, metal detection, ultrasound, isotope, or other suitable detection

methods, the location of identified tissue at any stage of a procedure or after an unsuccessful sampling attempt when the surgical field may be disturbed.

It would therefore be desirable to be able to provide a method and an apparatus that indicates the location of identified body tissue and guides the surgeon from the skin surface to the targeted tissue within the body and that includes a marker that is embedded in the tissue and is not subject to being displaced.

It would therefore also be desirable to be able to provide a method and an apparatus for identifying the location of a marker inside living tissue with the aid of visual, radiographic, imaging, scanning, metal detection, ultrasound, isotope, or other suitable detection techniques even if the surgical field is disturbed.

Summary of the Invention

It is an object of this invention to attempt to provide a method and an apparatus that indicates the location of identified body tissue and guides the surgeon from the skin surface to the targeted tissue within the body and that includes a marker that is embedded in the tissue and is not subject to being displaced.

It is a further object of this invention to attempt to provide a method and an apparatus for identifying the location of a marker inside living tissue with the aid of visual, radiographic, imaging, scanning, metal detection, ultrasound, isotope, or other suitable detection techniques even if the surgical field is disturbed.

In accordance with the principles of the invention, there is provided an apparatus for indicating the location of identified tissue in a living body. A marker is provided that is capable of being embedded in a region of tissue within the body. The marker is allowed to anchor itself within the tissue and lacks any portion that extends outside of the body. An elongated indicator is provided. The elongated indicator is also capable of being inserted in the tissue. The indicator has a distal end and a proximal end. The distal end is capable of being placed near the anchored marker within the tissue of the body in close proximity to the identified tissue. The proximal end of the indicator is allowed to remain outside the body to provide an indication of the location within the body of the identified tissue. A delivery device is also provided. The delivery device is capable of being inserted into the body and delivering the marker and a portion of the indicator to positions adjacent the identified tissue within the body.

Brief Description of the Drawings

The above and other objects and advantages of the invention will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which like reference characters refer to like parts throughout, and in which:

FIG. 1 is a perspective view of a woman's upper body showing a palpable, visible lump (exaggerated) in the breast;

FIG. 2 is a side elevational view of the lower portion of the woman's torso shown in FIG. 1 showing excision (exaggerated) of a lump;

FIG. 3a is a medio-lateral cross-section of a breast containing a lesion detected by imaging by high resolution mammography or ultrasound techniques;

FIG. 3b is a cranio-caudad cross-section of a breast containing a lesion detected by imaging by high resolution mammography or ultrasound techniques;

FIG. 4a is a side elevational view of the breast shown in FIG. 3 showing the lesion *in situ*;

FIG. 4b is a side elevational view of the breast shown in FIG. 3 showing the lesion as excised;

FIG. 5 is a side elevational view of the breast shown in FIG. 3 showing a straight needle inserted into the breast with the needle tip close to the abnormality;

FIG. 6 is a side elevational view of the breast shown in FIG. 3 containing a lesion showing how the guide needle is used to direct the incision;

FIG. 7 includes side elevational views showing "J-type" and "V-type" guide wires or indicators;

FIG. 8 is a side elevational view showing a guide wire threaded down the shaft of a delivery tube;

FIG. 9 is a side elevational view of the breast shown in FIG. 3 showing the tip of the "J-type" guide wire of FIG. 7 deployed on target through the tube of FIG. 8 and locked in the tissue within the breast;

FIG. 10 is a cross-section of the breast shown in FIG. 3 showing the distal end of the "J-type" guide wire of FIG. 7 deployed on target in the tissue

within the breast after the delivery tube of FIG. 8 has been removed;

FIG. 11 includes side elevational views of a variety of possible marker configurations;

FIG. 12 is a cross-section of the breast shown in FIG. 3 showing a straight tube positioned in the breast for delivery of a marker;

FIG. 13 is a cross-section of the breast shown in FIG. 3 showing a marker of a type illustrated in FIG. 12 in the bore of the tube of FIG. 12 positioned on target;

FIG. 14 is a cross-section of the breast of FIG. 3 showing a marker illustrated in FIG. 12 located in the bore of the delivery tube whose distal end is positioned on target near the lesion inside the breast and showing an indicator as in FIG. 7 having been inserted in the contracted state into the proximal end of the delivery tube;

FIG. 15 is a cross-section of the breast shown in FIG. 3 with delivery tube in place showing an indicator of FIG. 7 urging a marker of FIG. 12 out of the distal opening of the delivery tube and into the breast tissue in the targeted zone;

FIG. 16 is a cross-section of the breast shown in FIG. 3 with delivery tube in place showing the marker, having been urged along the length of the tube by an indicator of FIG. 7, fully deployed and locked in the target by its expansion into a relaxed state;

FIG. 17 is a cross-section of the breast shown in FIG. 3 with delivery tube in place and marker locked into place showing the further insertion and anchoring expansion of the distal end of an indicator of FIG. 7 into the breast tissue in the targeted zone;

FIG. 18a is a cross-section of the breast shown in FIG. 3 with marker and indicator locked into place showing configuration after delivery tube is removed from the breast;

FIG. 18b is a cross-section of the breast shown in FIG. 3 with marker and indicator locked into place within the breast and external portion of indicator secured to skin on surface of breast;

FIG. 19 is a cross-section of the breast shown in FIG. 3 with marker and indicator locked correctly into place showing schematically a proper incision that would result in a successful sample containing the marker, the indicator tip, and the lesion;

FIG. 20 is a cross-section of the breast shown in FIG. 3 with marker locked into place correctly near the lesion showing an indicator whose tip has been displaced away from the target region;

FIG. 21 is a cross-section of the breast shown in FIG. 3 with marker and indicator locked into place after the delivery tube is removed illustrating the incision and incorrect specimen that would result if the indicator were displaced after its insertion;

FIG. 22a is a cross-section of the breast shown in FIG. 3 after the displaced indicator, of the type shown in FIG. 19, is excised along with an incorrect specimen showing the embedded marker remaining locked in place near the target, thus allowing the surgeon to locate the target with imaging, metal detection, or other methods, return to the disturbed surgical field, and harvest a subsequent sample containing the lesion in a subsequent procedure as shown schematically;

FIG. 22b is a cross-section of the subsequent sample of FIG. 22a after the sample has been removed from the breast shown in FIG. 3;

FIG. 23 is a cross-section of the tube of FIG. 12 containing multiple markers;

FIG. 24 is a cross-section of the tube of FIG. 23 after insertion into the breast of FIG. 3, showing the deployment of some of the multiple markers of FIG. 23;

FIG. 25 is a cross-section of the breast of FIG. 3, showing the tube and multiple markers of FIG. 23 as deployed in a strategic pattern near a lesion;

FIG. 26 is a cross-section of the breast of FIG. 3 showing how markers deployed in pattern near a lesion bracket lesion and provide detailed guidance for location of incision;

FIG. 27a is a cross-section of the breast of FIG. 3 showing markers deployed in a pattern near a lesion and the trace of an incision that does not encompass the lesion because of a displaced indicator tip;

FIG. 27b is a cross-section of the breast of FIG. 3 after excision along the trace of FIG. 27a;

FIG. 27c is a cross-section of the sample excised from within trace of FIG. 27a;

FIG. 28a is a cross-section of the breast of FIG. 3 after the removal of the sample of FIG. 27c, showing a trace for a subsequent excision to encompass the constellation of markers of FIG. 25 and the bracketed lesion;

FIG. 28b is a cross-section of the sample excised according to the trace of FIG. 28a;

FIG. 29a is a perspective view of the invention packaged as a ready-to-use kit shown with closure removed;

FIG. 29b is a perspective view of the kit of FIG. 29a shown with closure in place; and

FIG. 30 is a plan view showing the elements of the kit shown in FIGS. 30a and 30b.

Detailed Description of the Invention

For purposes of illustration, the invention will be described for the most part in the context of its application to breast biopsy. It will be understood, however, that the invention can be used to indicate the location of an irregularity in the breast or elsewhere in a human or animal body, or in tissue to be identified for sampling, removal, or any other purpose; provide confirmable guidance to such identified tissue; permit at the operating table real-time confirmation of the presence or absence of the marker in an excised specimen and thus signal the success or failure of the attempted sampling of the identified tissue; assist a laboratory analyst in finding the identified tissue in the excised specimen when the identified tissue is non-palpable and unable to be easily recognized by the unaided eye; and, further, to permit reassessment of the operative site to pinpoint the location of identified tissue following a failed prior attempt to remove it.

Prior to the widespread use of X-ray mammography and ultrasonic examination, most abnormalities of a breast 10 (see FIG. 1) were recognized so late that they had attained the form of an easily identifiable lump 12 that deformed the

surface 14 of the breast or that could be easily felt under an undisturbed or minimally disturbed surface. Such a lump may have been sampled (or excised) successfully from the breast by incision 20 in a straightforward manner, as illustrated schematically in FIG. 2, because the lump was easily felt and seen. However, with the improvement of diagnostic techniques, even an extremely small abnormality 30 of breast 32 has become detectable (FIG. 3), thus introducing the possibility of the removal of identified tissue at such an early stage of development of a disease that the likelihood of a cure is increased. However, because a less distinctive lesion 30 is not palpable and does not deform the surface 34 of the breast and therefore is not visible, standard biopsy techniques based on tactile or visual guidance are not capable of reliably yielding a successful sample.

A marginally more advanced approach, known as visual mapping, has been developed to define the location of such lesions and guide the surgeon. Markings are drawn on the breast based on information from radiological films. However, the location of the identified tissue usually can be ascertained with resolution no greater than a breast quadrant. For example, in a breast having a lower portion 36, an upper portion 37, an inner portion 38, and an outer portion 39, a lesion 30 is located in the upper outer quadrant (FIG. 3). Thus, even with the drawn guide markings (not illustrated) exploratory cutting is required in the vicinity of the target and practitioners are required to excise a liberal portion 40 of tissue of breast 32 via excision 42, shown schematically in FIGS. 4A and 4B, in order to improve the likelihood of obtaining a specimen 40 that contains

lesion 30, thus generating substantial trauma for the patient. Even so, the sample often fails to contain the identified tissue, further excisions and sampling are required, and the breast is further traumatized.

In an improvement over visual mapping techniques, it has become known to insert a straight sharp needle 50, such as used for routine blood collection, into breast 32 to guide the surgeon to target 30 hidden within (FIG. 5). Guided by radiography, the tip 62 of the needle 50 is placed as close as possible to target 30 while the proximal portion 64 of the needle, remaining outside the breast, is secured to the skin with adhesive tape. Following needle 50, the surgeon makes an incision 66 and dissects down to the region of tissue near distal end 62 embedded in the region of the target and excises the lesion (FIG. 6).

However, since the needle 50 is smooth and is not anchored at its tip 62 inside the breast tissue, it is susceptible to being inadvertently displaced or withdrawn from the breast during patient manipulation. An imperceptible displacement could lead the surgeon astray and cause the wrong tissue to be sampled. Furthermore, there is potential for the needle to cause injury to medical personnel or the patient.

More recently, the basic needle method has been replaced by a method using a soft, blunt-ended tissue indicator, for example a wire such as those shown in FIG. 7 (70 or 74). Typically, the distal end (for example, 73 or 77) of the wire that is to be inserted into the breast is equipped with a curved hook 72 or an angular hook 76 (known as a "J"-type guide wire and a "V"-type guide wire, respectively). As shown in FIG. 8, sharp needle 50 is initially inserted

into breast 32 and tip 62 is placed near targeted lesion 30 as in earlier methods. Then, a soft guide wire, for example, "J"-type guide wire 70, is carefully fed in the direction of arrow "A" through hollow needle 50 until it emerges from tip 62. Upon deployment through opening 90 at the distal end of the tube, the springlike hook 72 unfurls and becomes locked into or near lesion 30 (FIG. 9). As shown in FIG. 10, needle 50 is then withdrawn from breast 32 leaving the hooked guide wire 70 in place. In surgery, the wire is used as a guide to make incision 100, as shown schematically in FIG. 10). Because the wire is anchored by the hook 72 inside the breast tissue, the likelihood of displacement is reduced.

However, in spite of the improved reliability obtained by inserting a hooked wire with the aid of a straight needle, the technique remains susceptible to errors caused by displacement of the needle and may lead to an unsuccessful biopsy procedure and the consequential trauma and delayed treatment.

The present invention supplements a soft biopsy indicator with an additional, self-anchoring independent marker, which may be of a variety different forms as illustrated in FIG. 11. As shown in FIG. 12, a hollow delivery tube is inserted into the breast with its leading tip placed in or near the lesion. A self-anchoring independent marker is delivered through the tube into the lesion or surrounding tissue (At the discretion of the surgeon, the marker may be placed close to the lesion, but preferably without disturbing the lesion to preferably maintain the lesion in a state of "clean margins." As used herein, the term "adjacent" includes, but is not limited to "next to" and "at least partially within".). An elongated

indicator with a self-anchoring tip is also fed through the tube (FIG. 14) and is used as a plunger to urge the marker through the bore of the tube and out the distal end of the tube (FIGS. 15 and 16) preferably in a substantially single maneuver, thus injecting the marker into the breast tissue. The indicator is further fed through the tube until it exits the distal end of the tube and is allowed to fasten itself near the marker (FIG. 17). The tube is then removed, leaving marker and indicator in place. The portion of the indicator that extends outside the patient's body is secured to the skin.

The indicator, like the guide wire discussed above, is useful for guiding the surgeon from the surface of the body to the lesion within, but extends outside the body and is thus subject to displacement as the patient's body is moved during the surgical procedure in spite of its anchored tip and secured proximal end.

The marker, however, is preferably biased to expand, preferably elastically, after it is expelled from the delivery tube inside the breast and engage the internal breast tissue. The marker has neither connection to the indicator wire nor any attachment to the external portion of the body and is therefore largely impervious to displacing forces that otherwise might tend to dislodge it from its substantially anchored position. The proximity of the distal end of the indicator and the marker can therefore be used to verify the placement of the indicator tip. The proximity may be evaluated using any visual, radiographic, scanning, ultrasound, isotope, or other suitable technique.

Additionally, the marker itself can be used in concert with any visual, isotopic, radiographic, ultrasonic, scanning, or other detection technique to confirm its position within the tissue or its presence within an excised specimen. It will be appreciated that, as used herein, radiographic techniques include, but are not limited to imaging or detection systems based on exposure to X-rays and that radiopaque materials are detectable by radiographic methods.

The invention will now be described in greater detail as it pertains to a variety of embodiments. In a preferred embodiment, the hollow delivery tube 120 preferably is a stainless steel needle such as that normally used for drawing blood. The needle preferably is inserted through the skin 123 into a region of a patient's breast 122 that contains a suspected lesion 126. Radiographic imagery or other medical imaging, detection, or scanning means may be used to insure that the tip 124, or distal end, of the needle is placed adjacent to or within the lesion while the opposite, or proximal, end 121 of the needle is maintained outside the body of the patient for the insertion and manipulation of markers and indicator wires.

As shown in FIG. 13, a marker, such as the preferably coil-shaped metallic spring of self-anchoring marker 114 (FIG. 11(c)), is provided to the region of the body adjacent to or within the lesion by inserting marker 114 into bore 128 of needle 120 through opening 130 at proximal end 121 of needle 120 and passing marker 114 through the length of needle 120. Marker 114 may be loaded into tube 120 before, after, or at any intermediate stage of inserting needle 120 into the body tissue.

Most preferably, the self-anchoring marker, which may be up to a few millimeters in length is preloaded in the needle, as is an indicator such as wire 70, forming a kit, and the entire kit preferably is sealed in a preferably sterile package, preferably for individual use.

In the compressed state of the marker 114, the coil-ends, prongs, or tines 115, which may themselves be equipped with secondary barbs (not shown), are retracted and the marker is able to fit slidably into the bore of the tube 120 (FIG. 13). After marker 114 has been driven from tube 120, prongs 115 preferably extend away from the center of the coil as the deformation strain relaxes and they engage or penetrate the surrounding body tissue, thus rendering marker 114 as a whole substantially unable to be displaced.

When marker 114 is loaded into bore 128 of guide needle 120 and needle 120 is adequately positioned, end 73 of an indicator wire such as 70 is inserted into opening 130 of proximal end 121 of needle 120 (FIG. 14) and wire 70 is threaded into needle 120 causing it to engage marker 114 and, like a plunger, urge marker 114 along bore 128 of needle 70 in the direction of arrow "B". When marker 114 reaches distal end 124 of needle 120 (FIG. 15), wire 70 is further fed into needle 120 to cause marker 114 to pass through distal opening 150 of tube 120 and into lesion 126 or surrounding tissue of breast 122 (FIG. 16). In this manner, marker 114 is deployed in or near the targeted suspect tissue whereupon it expands and secures itself within the tissue assisted by marker prongs 115.

Indicator wire 70 itself preferably has a self-anchoring feature at its distal end or tip 73. In

the preferred embodiment, it is a "J"-shaped spring hook 72 which then functions as the distal tip of indicator wire 70 (FIG. 7(b)). As shown in FIG. 17, after marker 114 is deployed, wire 70 preferably is fed further through needle 120 until hooked distal end 72 extends past opening 150 of distal end 124 of needle 120, whereupon self-anchoring hook 72 is released and preferably expands to engage the surrounding tissue, thus preferably securing distal end 72 of wire 70 near marker 114 within breast 122 (FIG. 17).

Indicator wire 70 preferably is sufficiently long that proximal end 71 extends outside breast 122 beyond skin 123 and beyond proximal end 121 of needle 120 (FIG. 17). With wire 70 held securely, needle 120 is withdrawn (FIG. 18a) leaving marker 114 and wire 70 in place. Wire 70 may then be secured to skin 123, for example, by tape 180 (FIG. 18b).

Two pointing devices are now preferably in position at the target site within breast 122. Indicator wire 70 protrudes from skin 123 and preferably provides a "line of sight" to help determine the optimal location for an incision. Marker 114, preferably substantially locked in position at identified tissue 126, has no extension to or beyond the surface of the body and is therefore substantially insensitive to being displaced by disturbances such as those caused by procedural motion near the surface of the body. Although such motions could displace indicator wire 70 as mentioned previously, they will have substantially no impact on independent marker 114.

During surgery, the surgeon preferably uses wire 70 to guide the opening of the surgical field and direct an incision 190 (shown schematically in FIG. 19) to the target 126. If at any time tip 72 of indicator

wire 70 and the marker 114 are found in close proximity by visual, imaging, or other detection means, the surgeon can remove sample 192 with confidence that wire 70 and tip 72 are in place, that he has been guided to the target, and that sample 192 contains indicator wire tip 72, marker 114, and lesion 126.

However, if wire 70 were displaced between its insertion and the sampling of lesion 126, distal end 72 of indicator wire 70 and embedded marker 114 would not be in close proximity to each other within breast 122 as illustrated in FIG. 20. This may be detected during the procedure and would provide evidence suggesting a reassessment of the surgical plan.

Alternatively, as shown in FIG. 21, displacement of indicator wire 70 or distal end 72 of indicator wire 70 may not be detected before the creation of an incision 210 to extract a sample 212. In this case, excised tissue sample 212 would contain end 72 of indicator wire 70, but not marker 114 or lesion 126, thus signaling a missed target.

In this case, however, the marker 114 remains in or near the target 126 and can continue to provide location guidance for subsequent searching and excision by making a secondary incision 220 to yield secondary sample 222 as shown schematically in FIG. 22a.

The searching, necessitated for example by a missed target, may be accomplished using scanning or imaging techniques that, without an embedded marker, would yield ambiguous information. The ambiguity of imaging techniques is especially problematic after a first surgery is initiated because of the lack of contrast between the lesion and the surgically traumatized or scarred surrounding tissue. The marker

114 also can be accurately localized at the surgical site with a metal detector. Any one of the scanning, imaging, or detection techniques, or a combination of them, using the independent marker as a target, may be used to reduce the number of samples that are required to track down a lost target.

In contrast, it may be that a sample is excised without the discovery of the self-anchoring marker and that there is a hypothesis that the marker is contained within the extracted tissue, such as sample 222 (FIG. 22b). Such a hypothesis may be easily tested by use of a metal detector, scanner, or imaging device. This provides the advantage of confirming that the targeted tissue was obtained before the surgical field is closed and is preferably accomplished in the operating theater or adjacent laboratory.

In the preferred embodiment, hollow delivery tube 120 is composed of stainless steel. However, it may also be composed of any stiff biologically inert material such as fluoropolymers (such as those sold under the trademark TEFLON®, by E.I. du Pont de Nemours & Company), polyethylene, other polymers or copolymers, or a composite.

Indicator 70 is preferably a stainless steel wire with a self-anchoring hook formed or attached on the end. Alternatively, indicator 70 may be composed of braided or monofilament polymer or wire with a self-anchoring hook formed on the end. In either the metallic or polymeric embodiments of the indicator, the self-anchoring hook may be either plastic or metal and may be formed from the indicator itself or welded, bonded, crimped, or otherwise fastened to the indicator. The indicator hook may be arranged in any

of the configurations described below in reference to the self-anchoring marker.

The self-anchoring marker 114 is preferably a coiled steel spring, but alternatively, may be "J"-shaped, "V"-shaped, serpentine, of a form shown in FIG. 11, or of a form derived from the forms shown in FIG. 11. It may also have variations of these shapes that include, but are not limited to shapes whose cross-sections follow substantially, are based on, or may be at least in part approximated by segments of a variety of plane curves such as a cycloid, trochoid, tractrix, evolute of an ellipse, folium of Descartes, or Cissoid of Diocles (see Spiegel, Murray R., Mathematical Handbook of Formulas and Tables, Schaum's Outline Series in Mathematics, McGraw-Hill Book Company, New York, 1968, chapter 11; as used herein, approximation may include, but is not limited to the use of quantitative mathematical methods or parameterization).

Alternatively, the marker may have a plurality of prongs 115 or tines, either of which may include barbs (not shown). The plurality of prongs or tines may extend three-dimensionally in a substantially pyramidal or conical configuration. The marker may also be configured as two substantially pyramidal or substantially conical portions arranged apex-to-apex for greater anchoring stability. In an embodiment described below, the marker may also be ellipsoidal or spheroidal.

The marker may be composed, among other materials, of metal, polymer, or a composite. Among other physical compositions, it may be solid or sintered. It is preferably radiopaque or has an appropriate density or acoustic velocity to yield an echo under acoustic or ultrasonic excitation when

disposed within the body tissue. In the metallic alternative, a shape memory alloy may be used to facilitate the engagement of the prongs with the surrounding tissue. In this embodiment, the "released" state of the marker is chosen to be stable at body temperature and the contracted state is chosen to be stable at a lower temperature which is maintained during the insertion of the marker through the delivery tube.

In an embodiment employing a polymeric marker, a metallic or otherwise radiopaque insert may be embedded within the marker to facilitate the detection feature of the invention by the use of radiographic methods such as X-ray methods or other forms of radiation. Either a metallic or non-metallic embodiment may be tagged with a radioactive material to facilitate location of the marker using radioactive decay detection means, such as a Geiger counter.

The marker may also contain one or more miniature passive reactive circuits, such as an RC, RL, or RLC circuit, whose presence is easily detected using a simple antenna and signal analysis instrumentation such as an oscilloscope.

In the sintered embodiments, the marker may be porous and permeable to enhance adhesion of the marker surfaces to the tissue. The pore space of a porous and permeable marker may also be filled with a bonding agent or chemical such as a biologically active adhesive to promote bonding with the surrounding tissue. Because of the enhanced adhesion feature of the sintered embodiments, ellipsoidal or spheroidal markers may be used. The pore space of such markers may also be filled wholly or in part with dye to enhance visual or radioactive detection.

In a further preferred embodiment of the invention, a plurality of self-anchoring markers such as marker 114 may be delivered to the tissue adjacent to the identified tissue within breast 122. The plurality of markers may preferably be of any one of the varieties described herein or may be of any combination thereof. Markers 234 may be loaded into a guide needle 230 after needle 230 is inserted in breast 122 or are preferably preloaded in needle 230 as shown in FIG. 23. Once needle 230 is inserted in breast 122, indicator wire 70 is used to expel markers 114 from opening 232 in distal end 236 of guide needle 230 as shown in FIG. 24.

An advantage of the multiple marker technique is that a marker pattern may be formed in the tissue surrounding identified tissue 126 in breast 122. In a particularly preferred embodiment of the multiple marker technique, guide needle 230 is used to install a series of markers 114 in a manner that surrounds, or brackets, identified tissue 126, as shown in FIG 25. Such an installation may require total or partial withdrawal of needle 230 in order to reposition distal end 236 of needle 230 for the deployment of each marker 114 of plurality 254 in preferably strategic locations in breast 122. Markers 114 can then be used collectively or individually as references against which to compare the position of distal end 72 of indicator wire 70, thus increasing the confidence with which the surgeon can elect to rely on the position of indicator wire 70 to direct incisions such as 260 (FIG. 26) for harvesting a sample from breast 122.

In the event of a displaced distal end 72 of indicator wire 70 and resulting unsuccessful excision of sample 272 defined by incision 270 (FIG. 27),

bracketing improves the accuracy with which the location of identified tissue in a breast or an excised tissue sample may be determined using visual, scanning, metal detection, ultrasound, isotope, radiographic, or other suitable detection techniques. This enables the surgeon to return to the surgical site to excise a new sample along incision such as 280 in FIG. 28. Samples such as 272 and 282 may be tested for confirmation of the presence of markers 114 of plurality 234, and thus identified tissue 126 using any of the aforementioned methods. Plurality 234 of markers is more easily detected than a single marker and therefore increases the ease and reliability of sample confirmation testing in the operating theater of laboratory. Furthermore, the multiple marker feature of the invention is easily provided as a feature of a kit such as that described below.

In yet another preferred embodiment, the apparatus is preferably provided as a sterilized ready-to-use kit 290, such as that shown in FIG. 29a, having a sealed plastic or otherwise impermeable tray 292 having a sterilized interior 294 and a preferably one-time removable closure 296 (FIG. 29b). Tray 292 is preferably molded plastic and has at least one recess 295. A delivery tube 120, an indicator 70 of ample length, and a marker such as 114 or plurality 234 of markers such as 114 (preferably disposed entirely inside tube 120) are disposed in a recess 295 of tray 292. Tube 120, indicator 70, anchor-equipped distal end 73 of indicator 70, and a self-anchoring marker 114 of kit 290 are shown in more detail in FIG. 30. In kit 290, marker or markers 114 and indicator 70 are preferably pre-loaded into delivery tube 120, are

preferably sterilized, and are preferably ready for immediate use upon removal of closure 296.

Alternatively, the invention may be packaged in a pouch (not shown) made of plastic, coated paper, or other impermeable material that is able to be sterilized, thus substituting for the packaging of tray 292 and closure 296.

A variety of kits may be provided together or separately that contain a different embodiments of the invention to provide the practitioner with a selection of indicators and markers, each of which may be most appropriate or effective for the particular tissue texture of a given patient.

Thus it is seen that an apparatus and a method for indicating the position of identified tissue during a biopsy procedure, for providing guidance to a surgeon for extracting a sample containing identified tissue from within the body using a tissue location indicator and a substantially immovable marker, for enabling the surgeon to ascertain if the indicator is properly positioned, and for identifying the location of an embedded marker inside living tissue with the aid of visual, scanning, or metal detection techniques have been provided. One skilled in the art will appreciate that the present invention can be practiced by other than the described embodiments, which are presented for purposes of illustration and not of limitation, and the present invention is limited only by the claims which follow.

WHAT IS CLAIMED IS:

1. An apparatus for indicating the location of identified tissue in a living body, said apparatus comprising:

a self-anchoring marker, said self-anchoring marker being adapted to be embedded within said living body and being allowed to be substantially locked into place within said living body adjacent said identified tissue;

an indicator having a distal end and a main body, said distal end of said indicator being adapted to be placed near said self-anchoring marker adjacent said identified tissue; and

a delivery device for insertion into said living body in an inserted position adjacent said identified tissue, said delivery device delivering said marker and at least a portion of said indicator to said living body from said inserted position.

2. The apparatus of claim 1 wherein said delivery device comprises:

a hollow delivery tube having openings on a proximal and a distal end, an inner diameter, and an outer diameter, said distal end being pointed for insertion through the skin of a living body,

said marker and said indicator being adapted to be inserted into said tube,

said indicator being adapted to urge said marker through said tube,

said indicator being adapted to expel said marker through said opening of said distal end of said tube and injecting said marker into said living body, and

said distal end of said indicator being adapted to be fed through said distal opening of said tube.

3. The apparatus of claim 2, wherein said tube is adapted to be removed from said living body while said marker and said indicator are allowed to remain substantially in position within said living body.

4. The apparatus of claim 2, wherein at least a portion of said tube comprises metal.

5. The apparatus of claim 1, further comprising at least one additional self-anchoring marker, each of said at least one additional self-anchoring marker being adapted to be embedded within said living body and being allowed to be substantially locked into place within said living body adjacent said identified tissue, to provide a plurality of self-anchoring markers within said body, and said delivery device being configured to deliver said additional markers to said living body.

6. The apparatus of claim 1, wherein said marker is adapted to be loaded into said delivery device before insertion of said delivery device into said body.

7. The apparatus of claim 1, wherein said indicator is adapted to be loaded into said delivery device before insertion of said delivery device into said body.

8. The apparatus of claim 1, wherein at least a portion of said marker is a biased engagement element.

9. The apparatus of claim 1, wherein at least a portion of said marker has a cross-section that is adapted to be substantially approximated by at least part of a "J".

10. The apparatus of claim 1, wherein at least a portion of said marker has a cross-section that is substantially serpentine.

11. The apparatus of claim 1, wherein at least a portion of said marker is substantially a coil.

12. The apparatus of claim 1, wherein at least a portion of said marker has a cross-section that is adapted to be substantially approximated by at least part of a trochoid.

13. The apparatus of claim 1, wherein at least a portion of said marker has a cross-section that is adapted to be substantially approximated by at least part of a tractrix.

14. The apparatus of claim 1, wherein at least a portion of said marker has a cross-section that is adapted to be substantially approximated by at least part of a folium of Descartes.

15. The apparatus of claim 1, wherein at least a portion of said marker has a cross-section that

is adapted to be substantially approximated by at least part of a cycloid.

16. The apparatus of claim 1, wherein at least a portion of said marker has a cross-section that is adapted to be substantially approximated by at least part of an evolute of an ellipse.

17. The apparatus of claim 1, wherein at least a portion of said marker has a cross-section that is adapted to be substantially approximated by at least part of a Cissoid of Diocles.

18. The apparatus of claim 1, wherein at least a portion of said marker has a cross-section that is adapted to be substantially approximated by at least part of a "V".

19. The apparatus of claim 1, wherein said marker further comprises at least one tine.

20. The apparatus of claim 1, wherein said marker further comprises at least one barb.

21. The apparatus of claim 1, wherein said marker further comprises at least one prong.

22. The apparatus of claim 1, wherein said marker further comprises at least one hook.

23. The apparatus of claim 1, wherein at least a portion of said marker comprises metal.

24. The apparatus of claim 1, wherein at least a portion of said marker is radiopaque.

25. The apparatus of claim 1, wherein said marker is tagged with radioactive material.

26. The apparatus of claim 1, wherein at least a portion of said marker is adapted to be located by scanning.

27. The apparatus of claim 1, wherein at least a portion of said marker is adapted to be located by imaging.

28. The apparatus of claim 1, wherein at least a portion of said marker is adapted to be located using ultrasound.

29. The apparatus of claim 1, wherein at least a portion of said distal end is radiopaque.

30. The apparatus of claim 1, wherein at least a portion of said distal end is adapted to be located by scanning.

31. The apparatus of claim 1, wherein at least a portion of said distal end is adapted to be located by imaging.

32. The apparatus of claim 1, wherein at least a portion of said distal end is adapted to be located using ultrasound.

33. The apparatus of claim 1, wherein at least a portion of said indicator is a metal wire.

34. The apparatus of claim 1, wherein said distal end of said indicator is equipped with an anchor that is adapted to engage tissue adjacent said identified tissue.

35. The apparatus of claim 34, wherein at least a portion of said anchor is a biased engagement element.

36. The apparatus of claim 34, wherein at least a portion of said anchor has a cross-section that is adapted to be substantially approximated by at least part of a "J".

37. The apparatus of claim 34, wherein at least a portion of said anchor has a cross-section that is substantially serpentine.

38. The apparatus of claim 34, wherein at least a portion of said anchor is substantially a coil.

39. The apparatus of claim 34, wherein at least a portion of said anchor has a cross-section that is adapted to be substantially approximated by at least part of a trochoid.

40. The apparatus of claim 34, wherein at least a portion of said anchor has a cross-section that is adapted to be substantially approximated by at least part of a tractrix.

41. The apparatus of claim 34, wherein at least a portion of said anchor has a cross-section that is adapted to be substantially approximated by at least part of a folium of Descartes.

42. The apparatus of claim 34, wherein at least a portion of said anchor has a cross-section that is adapted to be substantially approximated by at least part of a cycloid.

43. The apparatus of claim 34, wherein at least a portion of said anchor has a cross-section that is adapted to be substantially approximated by at least part of an evolute of an ellipse.

44. The apparatus of claim 34, wherein at least a portion of said anchor has a cross-section that is adapted to be substantially approximated by at least part of a Cissoid of Diocles.

45. The apparatus of claim 34, wherein at least a portion of said anchor has a cross-section that is adapted to be substantially approximated by at least part of a "V".

46. The apparatus of claim 34, wherein said anchor further comprises at least one tine.

47. The apparatus of claim 34, wherein said anchor further comprises at least one barb.

48. The apparatus of claim 34, wherein said anchor further comprises at least one prong.

49. The apparatus of claim 34, wherein said anchor further comprises at least one hook.

50. The apparatus of claim 34, wherein at least a portion of said anchor comprises metal.

51. The apparatus of claim 34, wherein at least a portion of said anchor is radiopaque.

52. The apparatus of claim 34, wherein said anchor is tagged with radioactive material.

53. The apparatus of claim 34, wherein at least a portion of said anchor is adapted to be located by scanning.

54. The apparatus of claim 34, wherein at least a portion of said anchor is adapted to be located by imaging.

55. The apparatus of claim 34, wherein at least a portion of said anchor is adapted to be located using ultrasound.

56. A kit for indicating the location of a region of concern in tissue of a living body, comprising:

a tray having at least one compartment therein;

a self-anchoring marker, said self-anchoring marker being adapted to be embedded within said living body and being allowed to be substantially locked into place within said living body;

an indicator having a distal end and a main body, said distal end of said indicator being adapted to be placed near said self-anchoring marker adjacent said identified tissue;

a delivery device for insertion into said living body in an inserted position adjacent said identified tissue, said delivery device delivering said marker and at least a portion of said indicator to said living body from said inserted position; and

a sealed removable closure allowing a user access to said tray, said marker, said indicator, and said delivery device; wherein:

said marker, said indicator, and said delivery device are disposed in a compartment of said tray.

57. The kit of claim 56, wherein said sealed removable closure is one-time removable.

58. The kit of claim 56 wherein said delivery device comprises:

a hollow delivery tube having openings on a proximal and a distal end, an inner diameter, and an outer diameter, said distal end being pointed and sharpened for insertion through the skin of a living body,

said marker and said indicator being adapted to be inserted into said tube,

said indicator being adapted to urge said marker through said tube,

said indicator being adapted to expel said marker through said opening of said distal end of said tube and injecting said marker into said living body, and

said distal end of said indicator being adapted to be fed through said distal opening of said tube.

59. The kit of claim 58, wherein said tube is adapted to be removed from said living body while said marker and said indicator are allowed to remain substantially in position within said living body.

60. The kit of claim 58, wherein at least a portion of said tube comprises metal.

61. The kit of claim 56, further comprising at least one additional self-anchoring marker, each of said at least one additional self-anchoring marker being adapted to be embedded within said living body and being allowed to be substantially locked into place within said living body adjacent said identified tissue, to provide a plurality of self-anchoring markers within said body, and said delivery device being configured to deliver said additional markers to said living body.

62. The kit of claim 56, wherein said marker is adapted to be loaded into said delivery device before insertion of said delivery device into said body.

63. The kit of claim 56, wherein said indicator is adapted to be loaded into said delivery device before insertion of said delivery device into said body.

64. The kit of claim 56, wherein at least a portion of said marker is a biased engagement element.

65. The kit of claim 56, wherein at least a portion of said marker has a cross-section that is adapted to be substantially approximated by at least part of a "J".

66. The kit of claim 56, wherein at least a portion of said marker has a cross-section that is substantially serpentine.

67. The kit of claim 56, wherein at least a portion of said marker is substantially a coil.

68. The kit of claim 56, wherein at least a portion of said marker has a cross-section that is adapted to be substantially approximated by at least part of a trochoid.

69. The kit of claim 56, wherein at least a portion of said marker has a cross-section that is adapted to be substantially approximated by at least part of a tractrix.

70. The kit of claim 56, wherein at least a portion of said marker has a cross-section that is adapted to be substantially approximated by at least part of a folium of Descartes.

71. The kit of claim 56, wherein at least a portion of said marker has a cross-section that is adapted to be substantially approximated by at least part of a cycloid.

72. The kit of claim 56, wherein at least a portion of said marker has a cross-section that is adapted to be substantially approximated by at least part of an evolute of an ellipse.

73. The kit of claim 56, wherein at least a portion of said marker has a cross-section that is adapted to be substantially approximated by at least part of a Cissoid of Diocles.

74. The kit of claim 56, wherein at least a portion of said marker has a cross-section that is adapted to be substantially approximated by at least part of a "V".

75. The kit of claim 56, wherein said marker further comprises at least one tine.

76. The kit of claim 56, wherein said marker further comprises at least one barb.

77. The kit of claim 56, wherein said marker further comprises at least one prong.

78. The kit of claim 56, wherein said marker further comprises at least one hook.

79. The kit of claim 56, wherein at least a portion of said marker comprises metal.

80. The kit of claim 56, wherein at least a portion of said marker is radiopaque.

81. The kit of claim 56, wherein said marker is tagged with radioactive material.

82. The kit of claim 56, wherein at least a portion of said marker is adapted to be located by scanning.

83. The kit of claim 56, wherein at least a portion of said marker is adapted to be located by imaging.

84. The kit of claim 56, wherein at least a portion of said marker is adapted to be located using ultrasound.

85. The kit of claim 56, wherein at least a portion of said distal end is radiopaque.

86. The kit of claim 56, wherein at least a portion of said distal end is adapted to be located by scanning.

87. The kit of claim 56, wherein at least a portion of said distal end is adapted to be located by imaging.

88. The kit of claim 56, wherein at least a portion of said distal end is adapted to be located using ultrasound.

89. The kit of claim 56, wherein at least a portion of said indicator is a metal wire.

90. The kit of claim 56, wherein said indicator, said marker, said tube, and at least interior surfaces of said tray and said closure have been sterilized.

91. The kit of claim 56, wherein said marker and said indicator are positioned within said tube.

92. The kit of claim 56, wherein said distal end of said indicator is equipped with an anchor that is adapted to engage tissue adjacent said identified tissue.

93. The kit of claim 92, wherein at least a portion of said anchor is a biased engagement element.

94. The kit of claim 92, wherein at least a portion of said anchor has a cross-section that is adapted to be substantially approximated by at least part of a "J".

95. The kit of claim 92, wherein at least a portion of said anchor has a cross-section that is substantially serpentine.

96. The kit of claim 92, wherein at least a portion of said anchor is substantially a coil.

97. The kit of claim 92, wherein at least a portion of said anchor has a cross-section that is adapted to be substantially approximated by at least part of a trochoid.

98. The kit of claim 92, wherein at least a portion of said anchor has a cross-section that is adapted to be substantially approximated by at least part of a tractrix.

99. The kit of claim 92, wherein at least a portion of said anchor has a cross-section that is adapted to be substantially approximated by at least part of a folium of Descartes.

100. The kit of claim 92, wherein at least a portion of said anchor has a cross-section that is adapted to be substantially approximated by at least part of a cycloid.

101. The kit of claim 92, wherein at least a portion of said anchor has a cross-section that is adapted to be substantially approximated by at least part of an evolute of an ellipse.

102. The kit of claim 92, wherein at least a portion of said anchor has a cross-section that is adapted to be substantially approximated by at least part of a Cissoid of Diocles.

103. The kit of claim 92, wherein at least a portion of said anchor has a cross-section that is adapted to be substantially approximated by at least part of a "V".

104. The kit of claim 92, wherein said anchor further comprises at least one tine.

105. The kit of claim 92, wherein said anchor further comprises at least one barb.

106. The kit of claim 92, wherein said anchor further comprises at least one prong.

107. The kit of claim 92, wherein said anchor further comprises at least one hook.

108. The kit of claim 92, wherein at least a portion of said anchor comprises metal.

109. The kit of claim 92, wherein at least a portion of said anchor is radiopaque.

110. The kit of claim 92, wherein said anchor is tagged with radioactive material.

111. The kit of claim 92, wherein at least a portion of said anchor is adapted to be located by scanning.

112. The kit of claim 92, wherein at least a portion of said anchor is adapted to be located by imaging.

113. The kit of claim 92, wherein at least a portion of said anchor is adapted to be located using ultrasound.

114. The kit of claim 92, wherein said marker and said indicator are positioned within said tube.

115. A method of indicating the location of identified tissue in a living body, said method comprising:

inserting a delivery device into said living body, said delivery device having a distal end and a proximal end, said distal end being placed adjacent said identified tissue and said proximal end being retained outside said body;

using said delivery device, inserting a marker into a region of tissue within said body adjacent said identified tissue, said marker lacking a portion that remains outside said body; and

using said delivery device, inserting an indicator having a proximal and a distal end, said distal end being placed near said marker and adjacent said identified tissue, and said proximal end remaining outside said body to provide an indication of the location within the body of the identified tissue.

116. The method of claim 115, wherein said inserting a delivery device comprises inserting a hollow tube having open proximal and distal ends through a surface of the living body, said distal end of said tube being placed in a position adjacent said identified tissue in said body and said proximal end being retained outside said body.

117. The method of claim 116, wherein said inserting a marker comprises placing said marker inside said hollow tube prior to said inserting of said indicator.

118. The method of claim 117, wherein said placing comprises loading said marker into said tube prior to said inserting a delivery device.

119. The method of claim 117, wherein said inserting an indicator comprises loading at least a portion of said indicator into said tube prior to said inserting a delivery device.

120. The method of claim 117, wherein said inserting an indicator comprises feeding said distal end of said indicator into said proximal end of said hollow tube after said placing of said marker inside said hollow tube.

121. The method of claim 120, wherein said inserting an indicator further comprises:

feeding said distal end of said indicator through said hollow tube, said indicator advancing said marker through said hollow tube, and

deploying said marker within said body adjacent said identified tissue by expelling said marker from said distal end of said tube; said method further comprising:

allowing said marker to become anchored in tissue adjacent said identified tissue.

122. The method of claim 121, further comprising:

passing said distal end of said indicator through said distal end of said tube; and

positioning said distal end of said indicator in tissue adjacent said identified tissue.

123. The method of claim 122, wherein said positioning said distal end further comprises allowing said distal end to become anchored in tissue adjacent said identified tissue.

124. The method of claim 122, further comprising extracting said hollow tube from said body, said indicator and said marker remaining substantially in place.

125. The method of claim 115, further comprising, after said inserting a marker, using said delivery device to insert at least one additional marker into said region of tissue within said body adjacent said identified tissue, each of said at least one additional marker lacking a portion that remains outside said body, to provide a plurality of markers in said region.

126. The method of claim 125, wherein said using said delivery device to insert at least one additional marker comprises bracketing said identified tissue.

127. The method of claim 115, further comprising assessing placement of said distal end of said indicator by comparing position of said distal end of said indicator with position of said marker.

128. The method of claim 127, wherein said assessing comprises using scanning techniques.

129. The method of claim 127, wherein said assessing comprises using imaging techniques.

130. The method of claim 127, wherein said assessing comprises using ultrasound techniques.

131. The method of claim 127, wherein said assessing comprises visual inspection.

132. The method of claim 127, wherein said assessing comprises using radiographic methods.

133. The method of claim 115, further comprising determining location of said marker using radioactive decay sensing techniques.

134. The method of claim 115, further comprising determining location of said marker using scanning techniques.

135. The method of claim 115, further comprising determining position of said marker using imaging techniques.

136. The method of claim 115, further comprising determining location of said marker using ultrasound techniques.

137. The method of claim 115, further comprising determining location of said marker by visual inspection.

138. The method of claim 115, further comprising determining location of said marker using metal detection techniques.

139. The method of claim 115, further comprising determining location of said marker using radiographic methods.

140. A method of testing for the presence of identified tissue in a sample excised from a living body, said method comprising:

inserting a delivery device into said living body, said delivery device having a distal end and a proximal end, said distal end being placed adjacent said identified tissue and said proximal end being retained outside said body;

using said delivery device, inserting a marker into a region of tissue within said body adjacent said identified tissue, said marker lacking a portion that remains outside said body; and

using said delivery device, inserting an indicator having a proximal and a distal end, said distal end being placed near said marker and adjacent said identified tissue, and said proximal end remaining outside said body to provide an indication of the location within the body of the identified tissue;

removing a specimen of tissue from said body; and

testing said specimen for presence of said marker.

141. The method of claim 140, wherein said inserting a delivery device comprises inserting a hollow tube having open proximal and distal ends through a surface of the living body, said distal end of said tube being placed in a position adjacent said identified tissue in said body and said proximal end being retained outside said body.

142. The method of claim 141, wherein said inserting a marker comprises placing said marker inside said hollow tube prior to said inserting of said indicator.

143. The method of claim 142, wherein said placing comprises loading said marker into said tube prior to said inserting a delivery device.

144. The method of claim 142, wherein said inserting an indicator comprises loading at least a portion of said indicator into said tube prior to said inserting a delivery device.

145. The method of claim 142, wherein said inserting an indicator comprises feeding said distal end of said indicator into said proximal end of said hollow tube after said placing of said marker inside said hollow tube.

146. The method of claim 145, wherein said inserting an indicator further comprises:

feeding said distal end of said indicator through said hollow tube, said indicator advancing said marker through said hollow tube, and

deploying said marker within said body adjacent said identified tissue by expelling said marker from said distal end of said tube; said method further comprising:

allowing said marker to become anchored in tissue adjacent said identified tissue.

147. The method of claim 146, further comprising:

passing said distal end of said indicator through said distal end of said tube; and

positioning said distal end of said indicator in tissue adjacent said identified tissue.

148. The method of claim 147, wherein said positioning said distal end further comprises allowing said distal end to become anchored in tissue adjacent said identified tissue.

149. The method of claim 147, further comprising extracting said hollow tube from said body, said indicator and said marker remaining substantially in place.

150. The method of claim 140, further comprising, after said inserting a marker, using said delivery device to insert at least one additional marker into said region of tissue within said body adjacent said identified tissue, each one of said at least one additional marker lacking a portion that remains outside said body, to provide a plurality of markers in said region.

151. The method of claim 150, wherein said using said delivery device to insert at least one additional marker comprises bracketing said identified tissue.

152. The method of claim 140, wherein said testing comprises detection of radioactive decay.

153. The method of claim 140, wherein said testing comprises scanning.

154. The method of claim 140, wherein said testing comprises imaging.

155. The method of claim 140, wherein said testing comprises ultrasound analysis.

156. The method of claim 140, wherein said testing comprises visual inspection.

157. The method of claim 140, wherein said testing comprises metal detection.

158. The method of claim 140, wherein said testing comprises using radiographic methods.

159. The method of claim 140, wherein said testing is conducted in an operating theater.

160. The method of claim 140, wherein said testing is conducted in a laboratory.

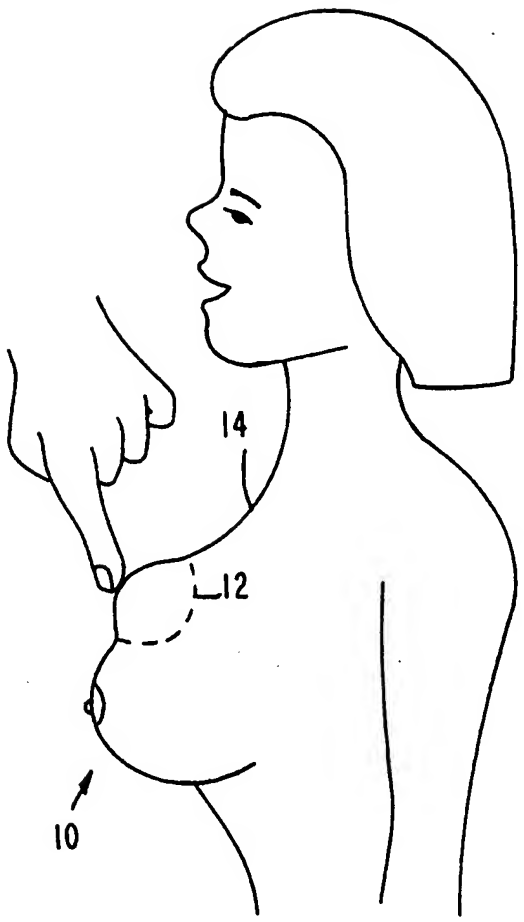


FIG. 1

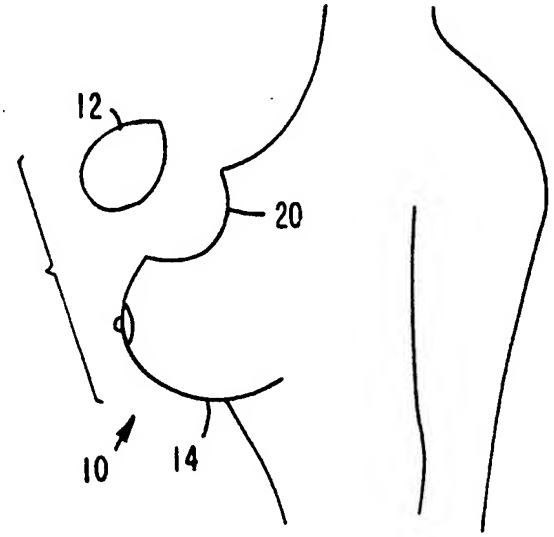


FIG. 2

FIG. 3a

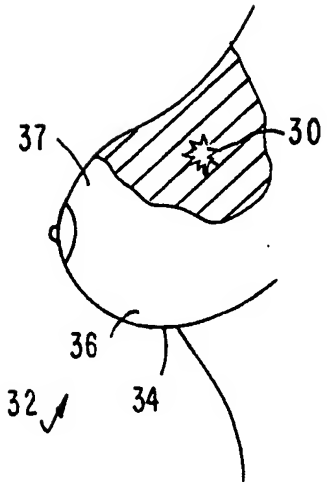
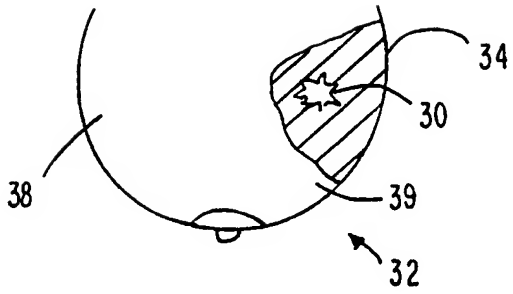


FIG. 3b



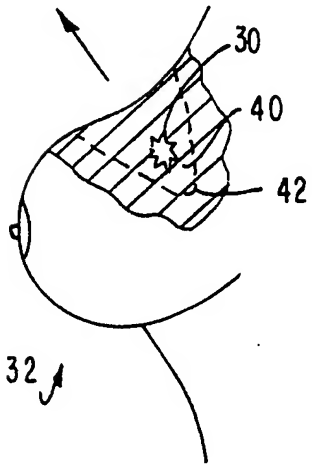


FIG. 4a

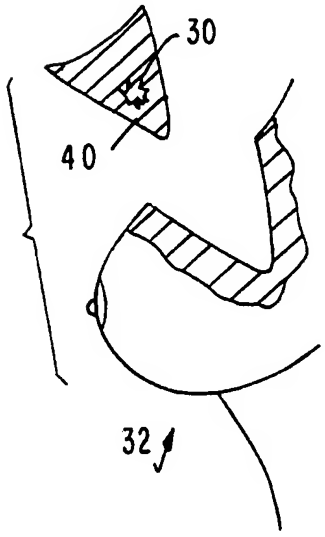


FIG. 4b

FIG. 5

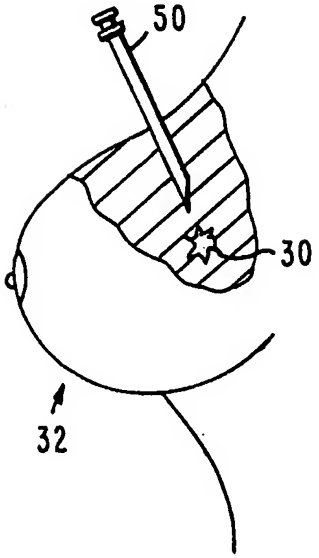


FIG. 6

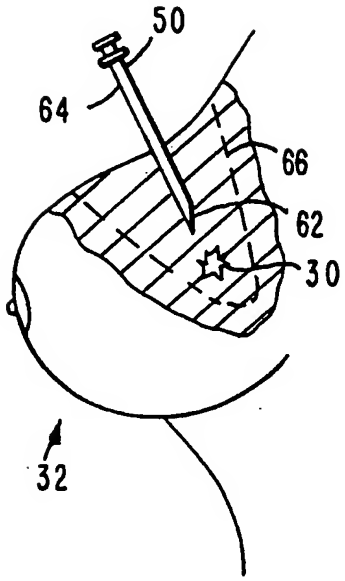
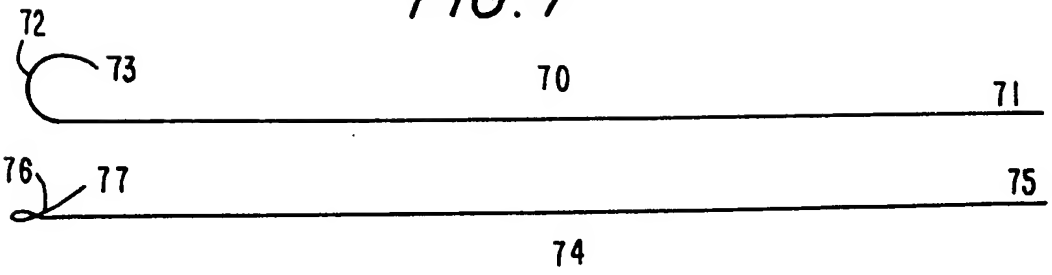


FIG. 7



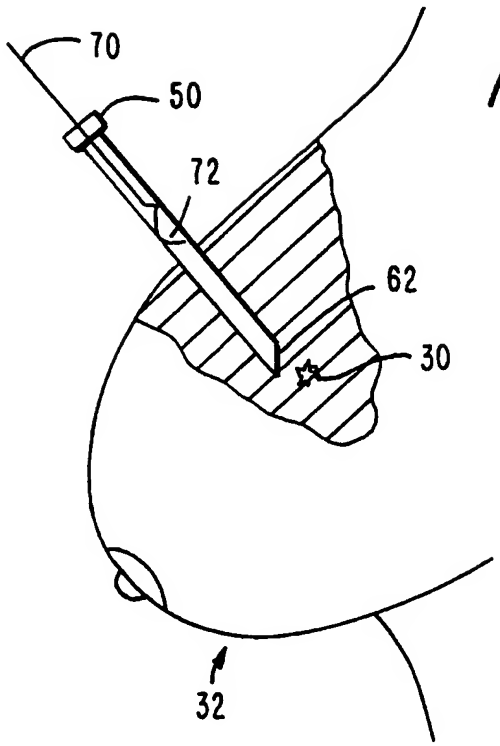


FIG. 8

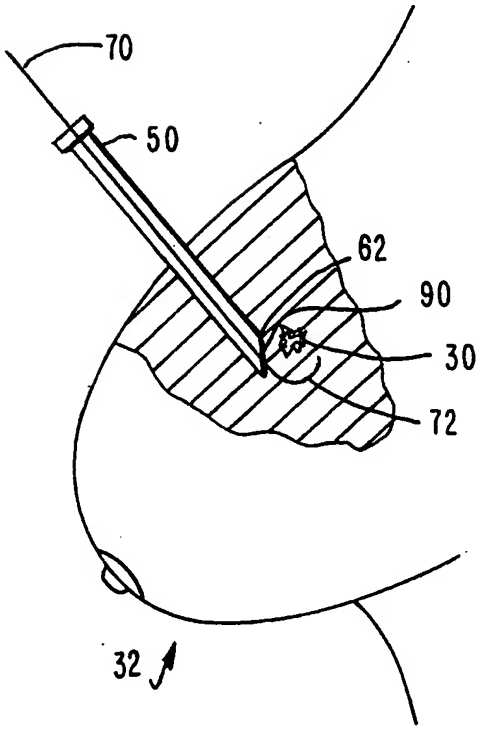


FIG. 9

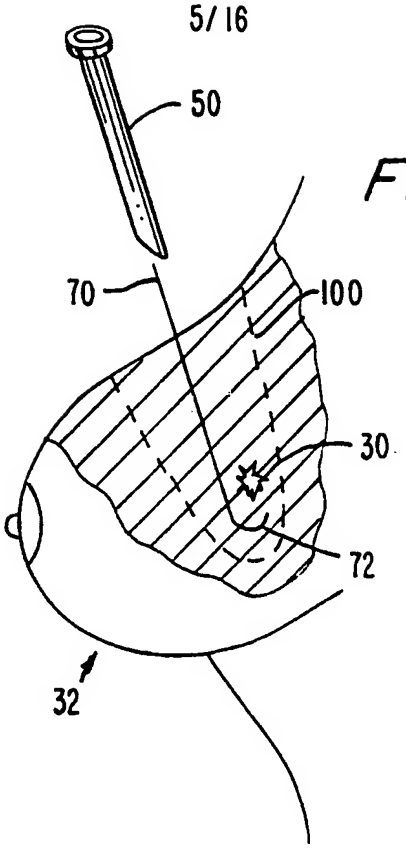


FIG. 10

FIG. 11a

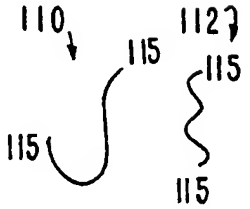


FIG. 11b

FIG. 11c

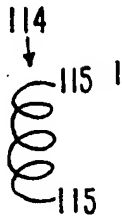


FIG. 11d

FIG. 11e

FIG. 11f

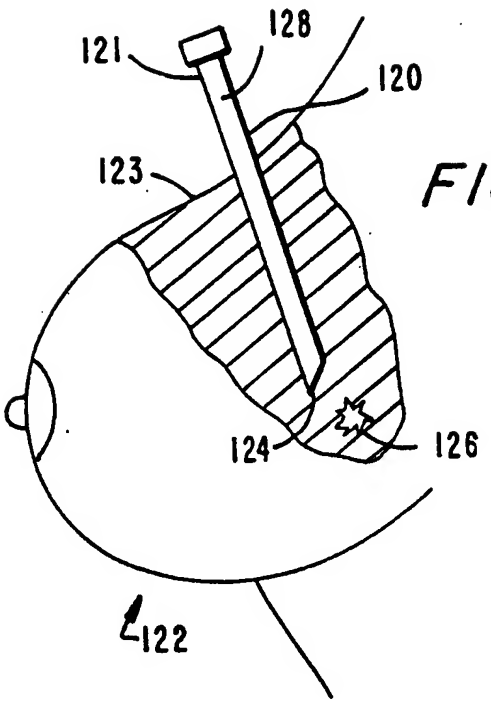


FIG. 12

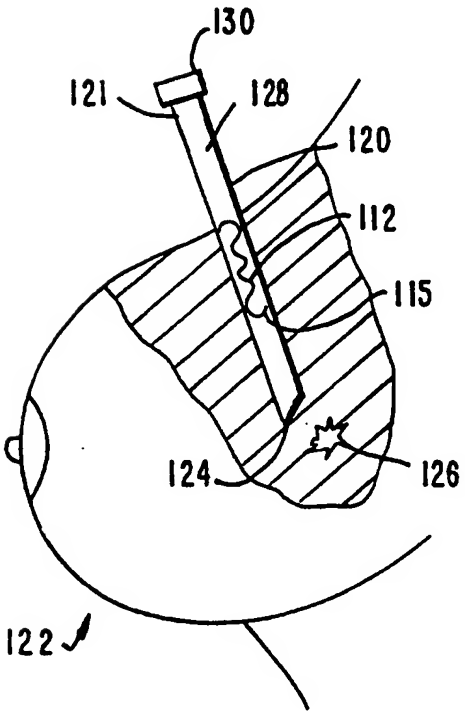
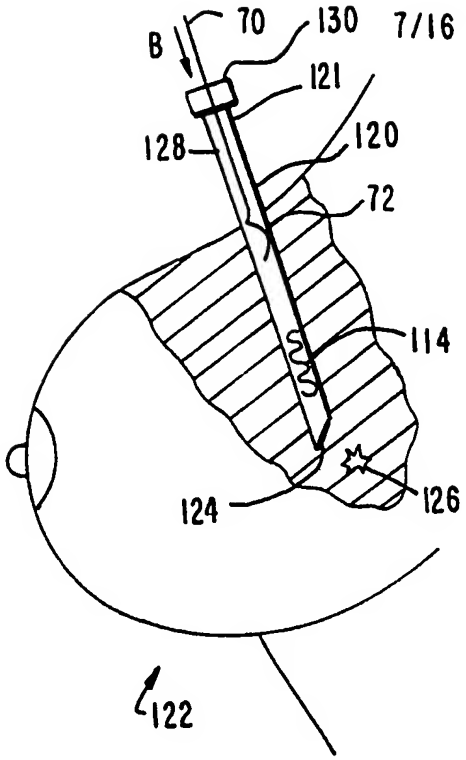


FIG. 13


B
70
130
121
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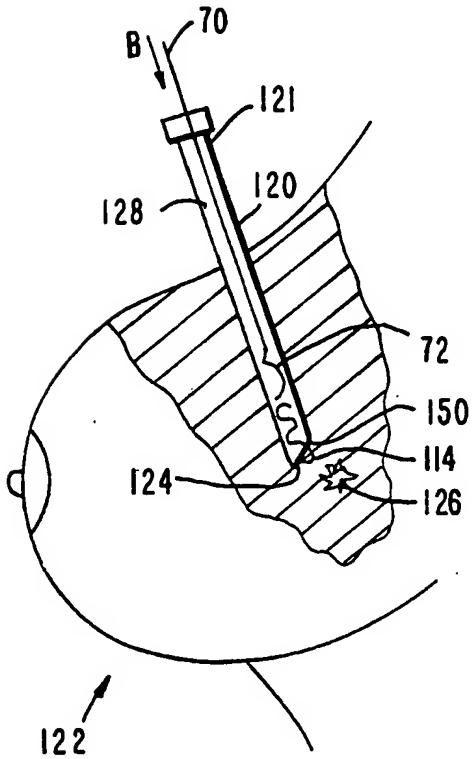
126
122

FIG. 14


B
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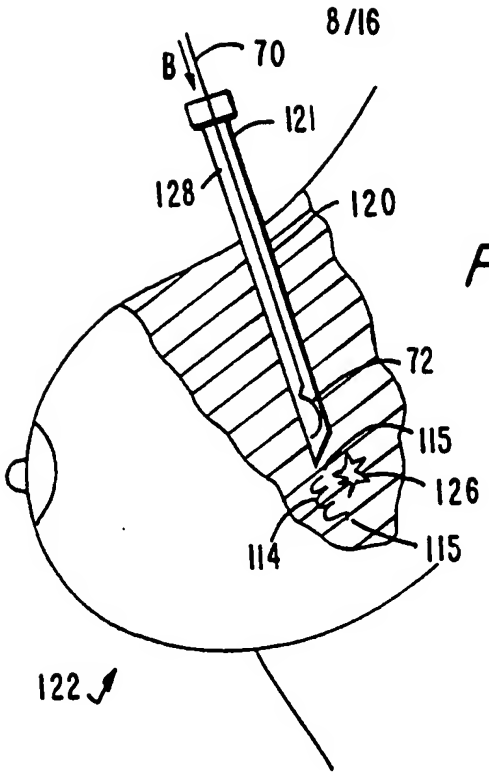
122

FIG. 15


B
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114
115
122

FIG. 16

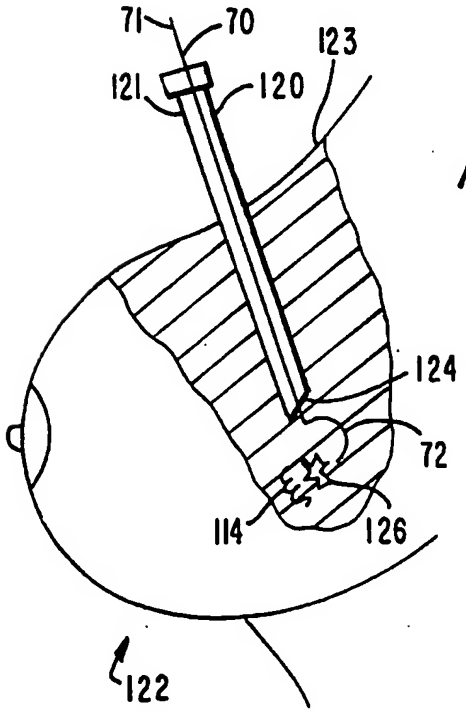
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FIG. 17

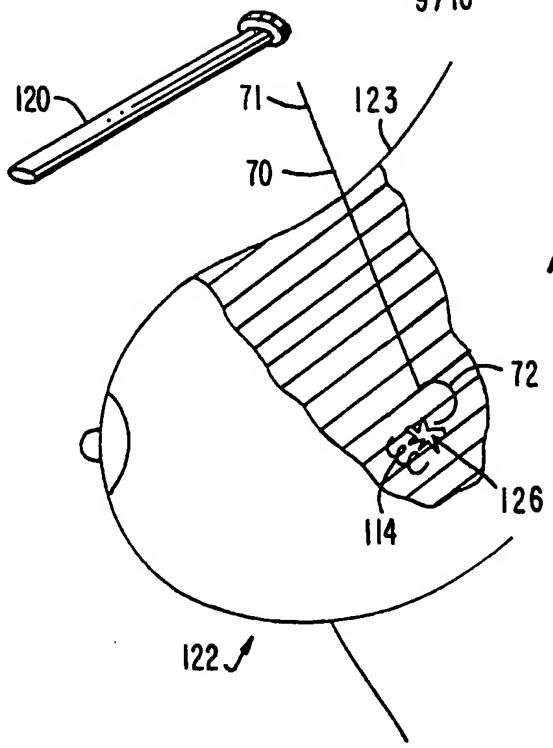


FIG. 18a

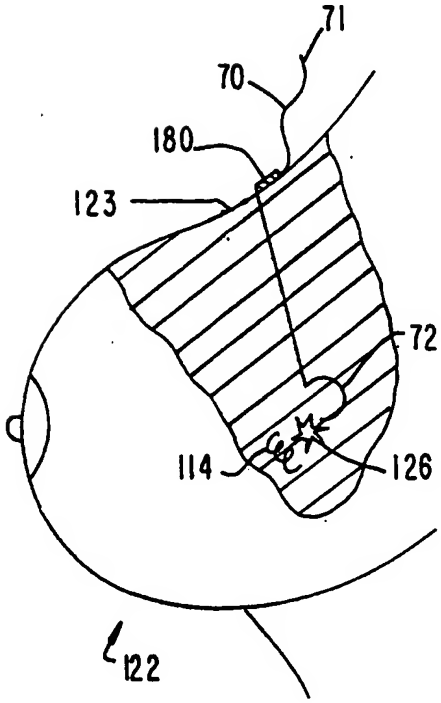


FIG. 18b

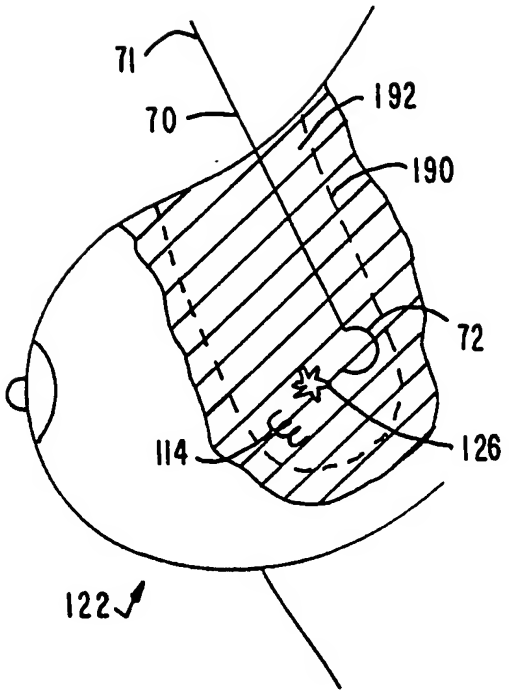


FIG. 19

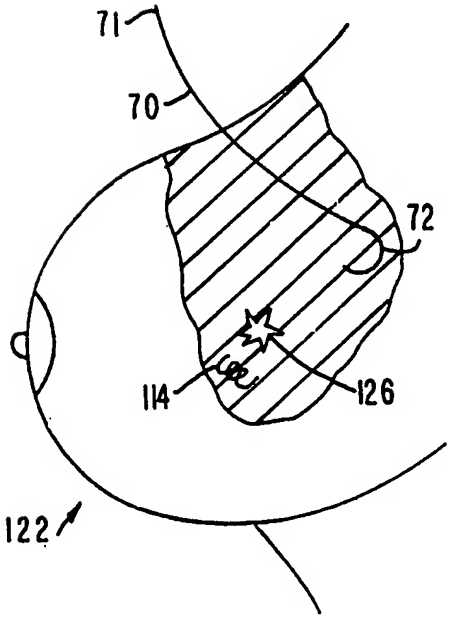


FIG. 20

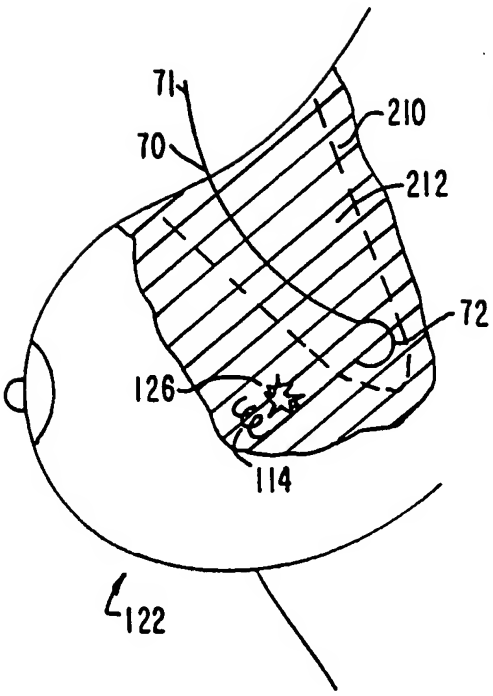
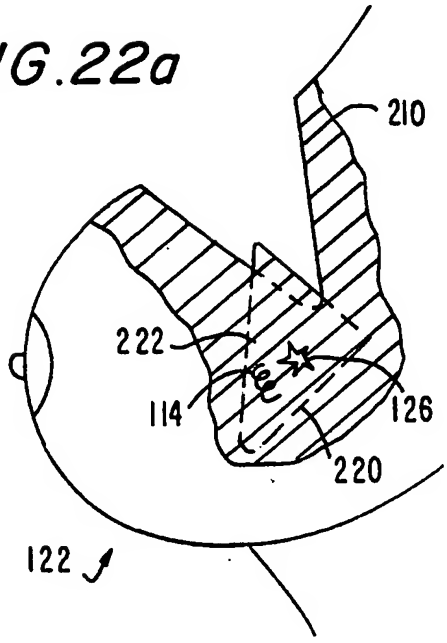


FIG. 21

FIG. 22a



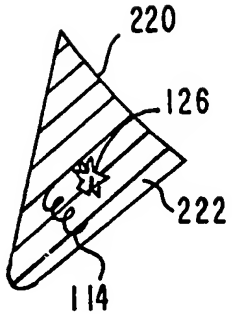
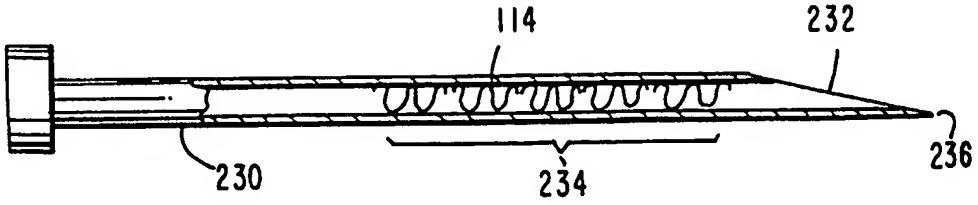


FIG. 22b

FIG. 23



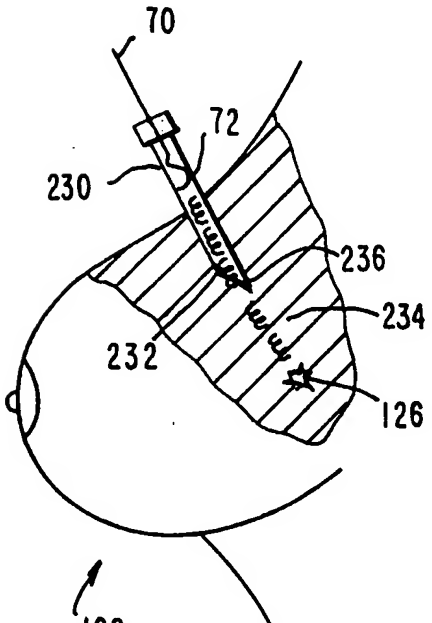


FIG. 24

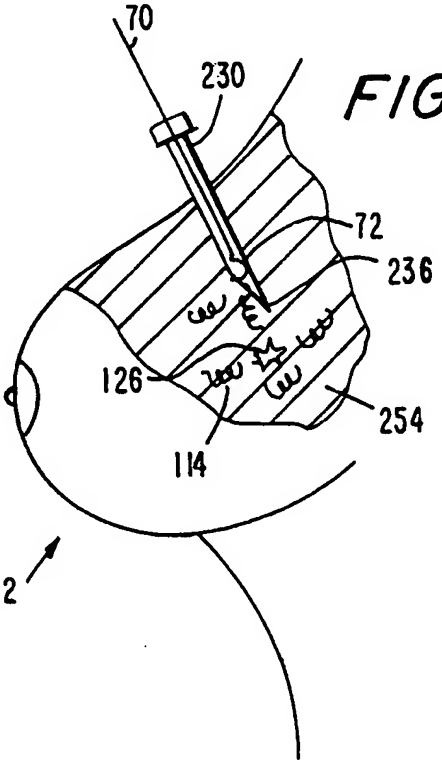


FIG. 25

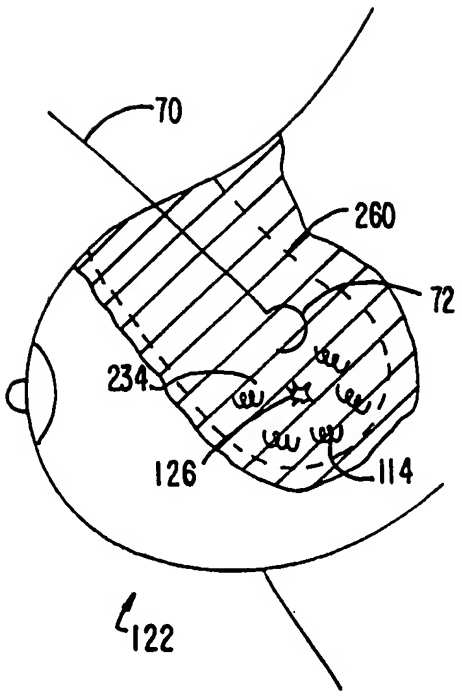


FIG. 26

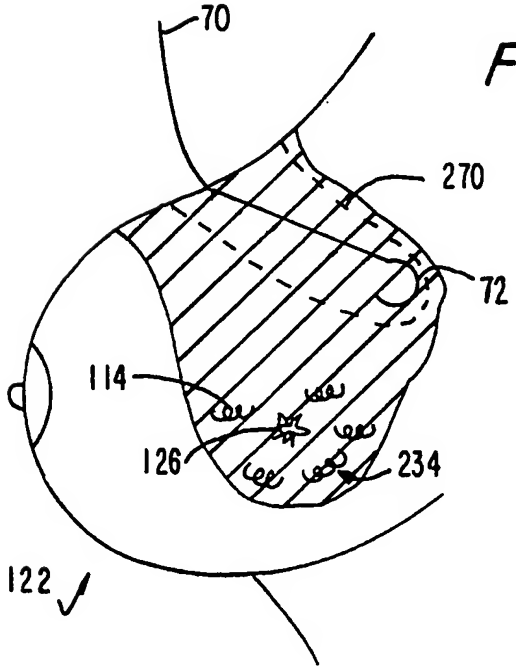
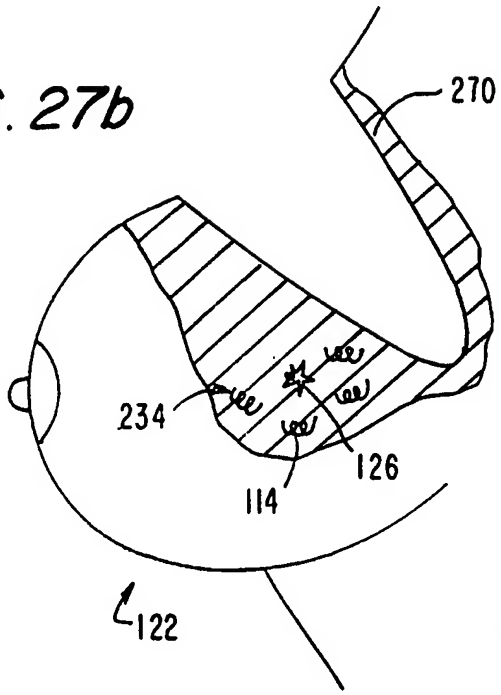


FIG. 27a

FIG. 27b



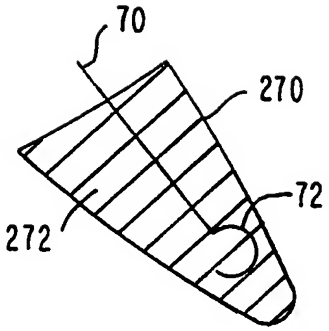
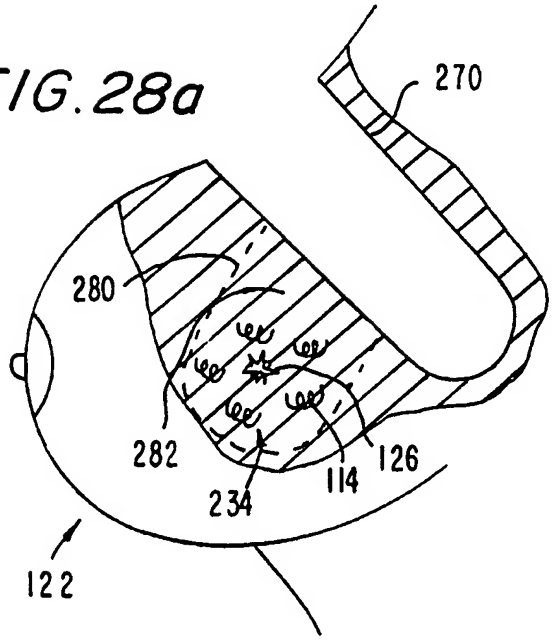


FIG. 27c

FIG. 28a



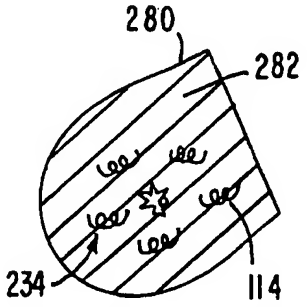


FIG. 28b

FIG. 29a

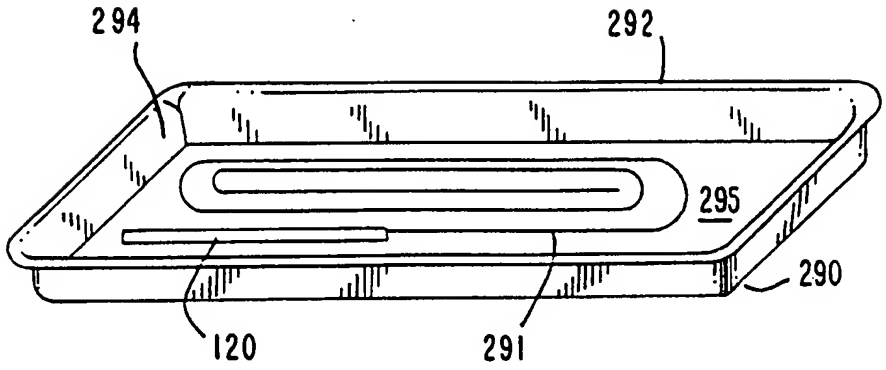


FIG. 29b

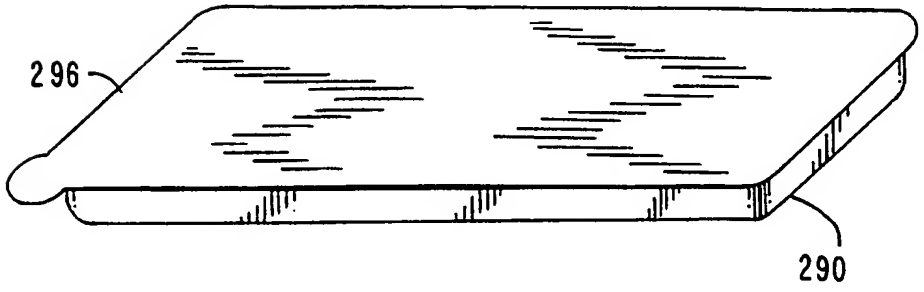
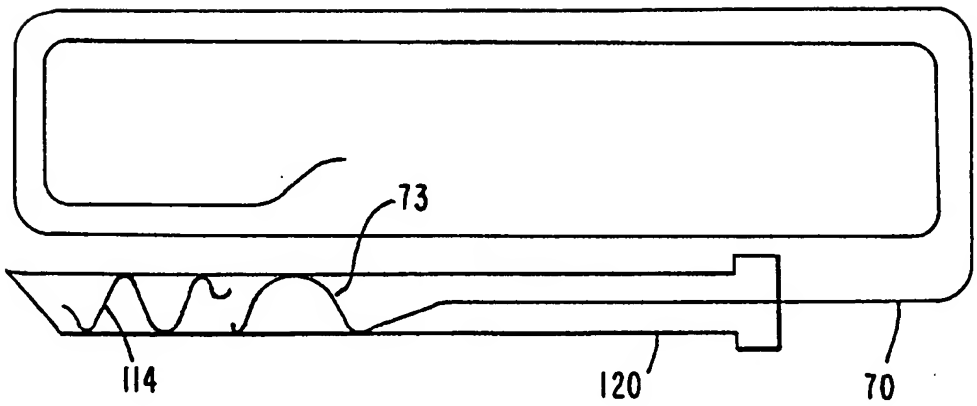


FIG. 30



INTERNATIONAL SEARCH REPORT

Inte. .ational Application No
PCT/US 99/24537

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 96 08208 A (BIOPSYS MEDICAL INC) 21 March 1996 (1996-03-21)	1-9, 11-15, 17-28, 30-36, 38-42, 44-57
A	page 18, line 1 - line 6; figures 12-20	29, 58-114

Y	WO 95 08958 A (M3 SYSTEMS INC) 6 April 1995 (1995-04-06)	1-9, 11-15, 17-28, 30-36, 38-42, 44-55
A	page 4, line 10 - line 26; figures 5,7,9	10,37, 56-114

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 January 2000	25/01/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Mayer, E

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inter. ..onal Application No
PCT/US 99/24537

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
Y	US 3 892 311 A (SNEIDER VINCENT R) 1 July 1975 (1975-07-01) column 5, line 45 - line 56; figures 1,5	56,57
A	WO 98 01068 A (KELSEY INC) 15 January 1998 (1998-01-15) page 13, line 4 - line 20; figures 1-3,7G	1,5,16, 43
A	US 5 647 374 A (CUTRER L MICHAEL) 15 July 1997 (1997-07-15) column 3, line 6 - line 9; figure 1	25,52

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 99/24537

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 115-160
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1 (iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter...donal Application No
PCT/US 99/24537

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9608208 A	21-03-1996	CA 2199864 A	21-03-1996
		EP 0781114 A	02-07-1997
		JP 10508504 T	25-08-1998
WO 9508958 A	06-04-1995	US 5556410 A	17-09-1996
		AU 7843994 A	18-04-1995
US 3892311 A	01-07-1975	NONE	
WO 9801068 A	15-01-1998	US 5853366 A	29-12-1998
		AU 3514597 A	02-02-1998
US 5647374 A	15-07-1997	NONE	